DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 13, 2014

Trophy Skin Incorporated
% Ms. Susan R. Anthoney-DeWet
AEGIS Regulatory Incorporated
2424 Dempster Drive
Coralville, Iowa 52241

Re: K133896
Trade/Device Name: Rejuvalite MD
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: October 6, 2014
Received: October 7, 2014

Dear Ms. Anthoney-DeWet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133896

Device Name
Rejuvalite MD

Indications for Use *(Describe)*
The Rejuvalite MD is an Over the Counter device that is intended for the use in the treatment of full face wrinkles.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K133896

This summary of 510(k) summary information is being submitted in accordance with the requirements of 21 CFR § 878.4810.

Submission Date: December 11, 2013

1. Submitter Information: AEGIS Regulatory, Inc. - Robert T. Wagner
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2. General Information

2.1 Classification Name: Light Based Over-The-Counter Wrinkle Reduction Device

2.2 Common/Usual Name: Rejuvalite MD

2.3 Proprietary Names: Rejuvalite MD

2.4 Classification: Class II

2.5 Classification Number: 878.4810

2.6 Product Code: OHS

2.7 Review Panel: General & Plastic Surgery

3. Device Description:

The Rejuvalite MD, is a tabletop device that contains 120 LEDs split evenly into 4 different wavelengths. The total power density for combined wavelengths is approximately 62 mW/cm2 at a distance of 4" from the illuminating surface of the device.

The labeling requires Users to maintain the distance between the illuminating surface and the treatment site at 4"during the treatment. There is a 4" distance limiting arm attached to the device to help users on determining and maintaining the 4" distance between the device's illuminating surface and the treatment site.

The Rejuvalite MD system components include the tabletop unit consisting of the base, arm, and swivel head containing the LED module , 4" distance limiting arm, timer, internal UL approved power adapter, and goggles.

The device incorporates a power adapter mounted inside of the lamp base that converts the AC to DC voltage. The power switch is operated to turn the device on or off.

The unit is designed to be placed on a table for easy exposure to the face to ensure consistent administration of light during each treatment. The device does not contain any user serviceable components. The device is sold as Over the Counter (OTC).

4. Indications / Intended Use:

The RejuvaliteMD is an Over –the- Counter device that is intended for the use in the treatment of full face wrinkles.

Rx or OTC:

> The Rejuvalite MD device is an Over the Counter (OTC) device. The labeling, instructions, and User Operations (21 CFR § 801.60 and 61), are designed for layman understanding and use. The predicate device is OTC.

5. Predicate Device (s):

This device is substantially equivalent to the following predicates, which are currently in safe and effective commerce:

1. **K120775 – LightStim for Wrinkles (LED Intellectual)**

Predicate Comparison Chart

Device	Rejuvalite MD Trophy Skin K133896 This Submission	LightStim for Wrinkles LED Intellectual K120775 A Predicate Device
Indications	The RejuvaliteMD is an Over the Counter device that is intended for the use in the treatment of full face wrinkles.	The Lightstim for Wrinkles is an OTC hand-held device intended for the use in the treatment of full-face wrinkles
Handheld	Table top	Yes
Wavelengths	600,622,660,860nm	605,630,660,855nm
Modes	On/Off	On/Off
Energy Source	120 LEDs. Over 90cm2	72 LEDs. Over 40cm2
Total Power Density	62 mW/cm2 at a distance of 4" from the LED head	62 mW/cm2 in contact with LED head
Power Supply	AC to DC	9-volt DC power transformer
Treatment Regime	3 minutes daily, 5 days per week for 8 weeks	3 minutes daily, 5 days per week for 8 weeks
Target Population	Individuals with wrinkles on the face	Individuals with wrinkles on the face
Location for Use	OTC	OTC

Summary of the technological characteristics of the device compared to predicate device:

The predicate device K120775 (LightStim for Wrinkles) has a smaller surface area with fewer LEDs than the proposed Rejuvalite MD device, but number of wavelengths, treatment duration, treatment regime and amount of energy (irradiance per area) delivered to the skin are the same.

This device also differs from the predicate device K120775 (LightStim for Wrinkles) in that it is not a handheld device in contact with the skin. The Rejuvalite MD is used at a 4" distance from the illuminated surface, but the power density per wavelength (mW/cm2), total power density of combined wavelengths (62 mW/cm2), amount of energy (irradiance per area) delivered to the skin measured at 4" are identical to the predicate device . The method of operation of the Rejuvalite MD device is similar to the predicate device K120775 (LightStim for Wrinkles) in that both devices have no software and use an On/Off switch.

No adverse effects on any of the predicate devices were found in MAUDE since clearance in 2005.

After analysis of safety, indications, intended uses, power density per wavelength (mW/cm2) , total power density of combined wavelengths (62 mW/cm2), performance, features, design materials, , technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer asserts that no significant differences exist between the applicant device and predicates listed in the predicate chart, and no new issues arise for safety and effectiveness. Therefore, substantial equivalency is hereby requested.

6. Biocompatibility:

The only patient contact material in the Rejuvalite MD is the body of the device.

The body of the device is constructed of ABS plastic, the same material used in the predicate device. The biocompatibility of this material is well known and considered safe when in contact with healthy skin.

The conclusion is that the Rejuvalite MD does not raise any new safety issues.

7. Performance Testing and Standards:

This device has been tested under and are in compliance with performance standards that have been established for such devices under Section 878 of the Federal Food, Drug, and Cosmetics Act.

Safety and functionality testing demonstrates that the Rejuvalite MD conforms to various international consensus standards:

IEC 60601-1: (2005) +Corr. 1 (2006) + Corr. + (2007): Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance.

IEC 60601-1-2: (2007): Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance: Collateral Standard: Electromagnetic Compatibility

Performance Testing on optical and electrical characteristics demonstrated that the Rejuvalite MD device is almost identical to that of the predicate devices.

A Usability/Label Comprehension Study was conducted with 36 participants.

The results of the study found that:
97% of the participants were able to comprehend the labeling.
100% of the participants were able to use the device successfully.

The conclusions drawn from nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed devices.

8. Statement of Safety and Effectiveness:

The information in this 510(k) submission was used to support the safety and effectiveness of this device with respect to its cited predicates.

9. Substantial Equivalence Discussion

After analysis of safety, indications, intended uses, power density (mW/cm2) per wavelength, total power density of combined wavelengths (62 mW/cm2), performance, features, design materials, technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer asserts that no significant differences exist between the applicant device and predicates listed in the predicate chart, and no new issues arise for safety and effectiveness. Therefore, substantial equivalency is hereby requested.